REMARKS

Claims 16-28 were pending in the application at the time the Office Action was mailed. Claims 16-27 were rejected. Claim 28 was withdrawn as being directed to non-elected subject matter. Claims 16-27 were objected to for being misnumbered. Because the Office Action states that misnumbered claims 21-27 have been renumbered 22-28, Applicants understand that the examiner has renumbered these claims and that the objection is not outstanding. Claims 16-27 were rejected. No claims were allowed.

By this amendment, claims 16-22 and 24-27 have been amended. Claim 23 has been canceled. No claims have been added. Therefore, claims 16-22 and 24-28 remain pending in the application.

Amendments to the Specification and Claims 17 and 20

Paragraphs [0043] and [0076] of the specification and claims 17 and 20 have been amended herein to include the limitation "linkage disequilibrium." Support for "linkage disequilibrium" can be found in the application as filed in paragraphs [0043] and [0076] which recite "chain imbalance" and have been amended herein to instead recite "linkage disequilibrium." The present application is a US national phase application claiming priority to Japanese patent application numbers 2002-42355 and 2002-213695 which recite "rensa-fuheikou". The English translation of the Japanese applications translated "rensa-fuheikou" to "chain imbalance." However, Applicants submit that "linkage disequilibrium" is a more accurate translation of " rensa-fuheikou" and that amending the claims and specification to recite "linkage disequilibrium" does not constitute new matter. Attached hereto is a copy of three pages from a Japanese translation of Jurg Ott's textbook entitled "Analysis of Human Genetic Linkage" evidencing that "linkage disequilibrium" is translated as "rensa-fuheikou" in the Japanese language.

Claim Rejections Under 35 U.S.C. § 112

Claims 1-27 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-15 were previously canceled. Misnumbered claims 16-27 have been renumbered 16-28 and claim 28 has been withdrawn. Claim 23 has been canceled. Claims 16-22

and 24-27 have been amended herein to address each rejection under 35 U.S.C. 112, second paragraph.

Accordingly, withdrawal of these rejections is respectfully requested.

Claim Rejections Under 35 U.S.C. § 101

Claims 16-27 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. According to the Office Action:

> The claims are directed to methods of "specifying" SNP information that may be related to disease susceptibility or drug responsiveness. The claims do not recite statutory methods under 35 USC 101. The recited claims do not set forth any transformation of matter, nor do they provide a concrete, tangible and useful result. The result of claim 16 is a "target SNP" which is merely a piece of sequence information/data which differs in a single aspect from an unspecified reference. The SNP data is not linked to any particular disease susceptibility or drug response. The SNP information is not tangible or output to any user. The SNP data requires further interpretation or manipulation to be used or understood. The method does not produce *a* concrete result, as there is no assurance that any SNP will be found to be linked in any particular domain to the desired trait.

As amended herein, claim 16 (from which claims 17-22 and 24-27 depend) recites: "A method of identifying a single nucleotide polymorphism (SNP) that causes disease susceptibility or responsiveness to a drug comprising: obtaining data from a case group and data from a control group; defining a scanning domain for a gene thought to cause disease susceptibility or responsiveness to a drug or defining a scanning domain in a genomic region or in one or more chromosomes thought to cause disease susceptibility or responsiveness to a drug; selecting SNPs to obtain data by SNP haplotyping analysis in the scanning domain; defining a base sequence domain that contains a specified number of SNPs determined by a range of several SNPs to several hundred SNPs as a window, and shortening the physical distance of the scanning domain

by estimating the base sequence domain near a target SNP that causes susceptibility to a disease or responsiveness to a drug by using the data of the selected SNPs; identifying said target SNP in the shortened scanning domain; and correlating the target SNP with responsiveness to a drug or with susceptibility to a disease."

Applicants submit that the claims as amended herein do result in a useful, concrete and tangible result, i.e., identifying an SNP that causes disease susceptibility or responsiveness to a drug. Thus, the claims as currently amended constitute statutory subject matter under §101.

Withdrawal of this rejection is therefore respectfully requested.

Claim Rejections Under 35 U.S.C. § 102

Claims 16-27 were rejected under 35 U.S.C. 102(e) as being anticipated by Margus (U.S. patent no. 6,955,883). According to the Office Action:

> Margus et al. (US 6,955,883 having priority to 3/26/02) discloses life science business models which obtain genomic information from a variety of populations and individuals, define domains or stretches of DNA which may contain SNP's of interest, identify SNP's within the domains, and specify targets, The targets may be associated with drug responsiveness or disease susceptibility. Wet steps of SNP typing may be performed, and statistical analyses of the significance of the findings can be performed. As such, Margus anticipates the methods of the claims.

As amended herein, claim 16 (from which claims 17-22 and 24-27 depend) recites: "A method of identifying a single nucleotide polymorphism (SNP) that causes disease susceptibility or responsiveness to a drug comprising: obtaining data from a case group and data from a control group; defining a scanning domain for a gene thought to cause disease susceptibility or responsiveness to a drug or defining a scanning domain in a genomic region or in one or more chromosomes thought to cause disease susceptibility or responsiveness to a drug; selecting SNPs

to obtain data by SNP haplotyping analysis in the scanning domain; defining a base sequence domain that contains a specified number of SNPs determined by a range of several SNPs to several hundred SNPs as a window, and shortening the physical distance of the scanning domain by estimating the base sequence domain near a target SNP that causes susceptibility to a disease or responsiveness to a drug by using the data of the selected SNPs; identifying said target SNP in the shortened scanning domain; and correlating the target SNP with responsiveness to a drug or with susceptibility to a disease."

Unlike the claimed invention, which provides for identifying an SNP that causes disease susceptibility or responsiveness to a drug without the need for analyzing all SNPs over a very large region, Margus discloses methods that require analyzing all SNPs over more than 10,000,000 bases. Because Margus does not teach the limitations of "defining a scanning domain for a gene thought to cause disease susceptibility or responsiveness to a drug or defining a scanning domain in a genomic region or in one or more chromosomes thought to cause disease susceptibility or responsiveness to a drug;" and "selecting SNPs to obtain data by SNP haplotyping in the scanning domain," claims 16-22 and 24-27 are not anticipated by this reference.

Accordingly, withdrawal of this rejection is respectfully requested.

Claims 16-27 were rejected under 35 U.S.C. 102(e) as being anticipated by Ramnarayan et al. According to the Office Action:

> Ramnarayan et al. (US 2003/0158672 having priority to 11/10/2000) discloses methods of using SNP information to generate 31) models of drug targets, These methods obtain genomic information for genes or proteins which are targets of a defined drug from *a variety* of populations and individuals, define domains or stretches of DNA within those sequences which may contain SNP's of interest, identify SNP's within the domains, and specify targets. The targets may be associated with drug responsiveness. Wet steps of SNP typing may be performed, and statistical analyses of the significance of the findings can be performed. As such, Ramnarayan anticipates the methods of the claims.

As amended herein, claim 16 (from which claims 17-22 and 24-27 depend) recites: "A method of identifying a single nucleotide polymorphism (SNP) that causes disease susceptibility or responsiveness to a drug comprising: obtaining data from a case group and data from a control group; defining a scanning domain for a gene thought to cause disease susceptibility or responsiveness to a drug or defining a scanning domain in a genomic region or in one or more chromosomes thought to cause disease susceptibility or responsiveness to a drug; selecting SNPs to obtain data by SNP haplotyping analysis in the scanning domain; defining a base sequence domain that contains a specified number of SNPs determined by a range of several SNPs to several hundred SNPs as a window, and shortening the physical distance of the scanning domain by estimating the base sequence domain near a target SNP that causes susceptibility to a disease or responsiveness to a drug by using the data of the selected SNPs; identifying said target SNP in the shortened scanning domain; and correlating the target SNP with responsiveness to a drug or with susceptibility to a disease."

Because Ramnarayan et al. does not teach the limitations of "identifying an SNP that causes disease susceptibility or responsiveness to a drug" or "correlating the target SNP with responsiveness to a drug or with susceptibility to a disease", claims 16-22 and 24-27 are not anticipated by this reference. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 16-27 were rejected under 35 U.S.C. 102(a) as being anticipated by Xu (GLAXO WO 2002/20835). According to the Office Action:

> Xu et al. (WO 2002/20835, published 3/14/02: PTO-1449) discloses methods of associating phenotypes with haplotypes. These methods obtain genomic information from a variety of populations and individuals, define domains or stretches of DNA which may contain SNP's of interest, identify SNP's within the domains, and specify targets. The targets may be associated with phenotypes such as drug responsiveness or disease susceptibility. Wet steps of SNP typing may be

performed, and statistical analyses of the significance of the findings can be performed. As such, Xu anticipates the methods of the claims.

As amended herein, claim 16 (from which claims 17-22 and 24-27 depend) recites: "A method of identifying a single nucleotide polymorphism (SNP) that causes disease susceptibility or responsiveness to a drug comprising: obtaining data from a case group and data from a control group; defining a scanning domain for a gene thought to cause disease susceptibility or responsiveness to a drug or defining a scanning domain in a genomic region or in one or more chromosomes thought to cause disease susceptibility or responsiveness to a drug; selecting SNPs to obtain data by SNP haplotyping analysis in the scanning domain; defining a base sequence domain that contains a specified number of SNPs determined by a range of several SNPs to several hundred SNPs as a window, and shortening the physical distance of the scanning domain by estimating the base sequence domain near a target SNP that causes susceptibility to a disease or responsiveness to a drug by using the data of the selected SNPs; identifying said target SNP in the shortened scanning domain; and correlating the target SNP with responsiveness to a drug or with susceptibility to a disease."

Because Xu does not teach the limitations of "identifying an SNP that causes disease susceptibility or responsiveness to a drug" or "correlating the target SNP with responsiveness to a drug or with susceptibility to a disease", claims 16-22 and 24-27 are not anticipated by this reference.

Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

The currently pending claims before the examiner are supported throughout the specification and are patentable over the prior art. No new matter has been added. This application is now in full condition for allowance, and such action is respectfully requested.

This Amendment is accompanied by a retroactive petition for a one month extension of time and the required fees. Although Applicant believes that no further extensions of time are required with submission of this paper, Applicant requests that this submission also be considered as a petition for any further extensions of time if necessary. The Commissioner for Patents and Trademarks is hereby authorized to charge the amount due for any extensions of time and any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

The examiner is cordially invited to call the undersigned if clarification is needed on any matter within this Amendment, or if the examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

AKERMAN SENTERFITT

Date: July 17, 2008

Amy A. Dobbelaere, Ph.D.
Reg. No. 52,088
AKERMAN SENTERFITT
P.O. Box 3188
West Palm Beach, FL 33402-3188
Tel: 561-653-5000

Docket No. 3883.021

[Based on this book]

Analysis of Human Genetic Linkage Third Edition

by

JURG OTT

監訳者紹介

五條堀 孝

1974年　九州大学理学部生物学科卒業．理学博士
現　在　国立遺伝学研究所 生命情報・DDBJ研究センター長
総合研究大学院大学生命科学研究科 教授（併任）
独立行政法人産業技術総合研究所生物情報解析センター
副センター長（併任）
主要著書　人間は生命を創れるか―進化学のあゆみと未来，丸善ライブラリー（1995年）；ゲノム情報を読む，共立出版（1997年）など

訳者紹介

安田 徳一

1958年　早稲田大学第一理工学部数学科卒業．Ph. D in Genetics
放射線医学総合研究所，国立遺伝学研究所などを経て
現　在　独立行政法人産業技術総合研究所生物情報解析センター
特別研究員
主要著書　人のための遺伝学，裳華房（1994年）．主要訳書　基礎集団遺伝学，培風館（1989年）；人類遺伝学，朝倉書店（1989年）など

NDC491　230p　27cm

ヒトゲノムの連鎖分析―疾患遺伝子の探索

2002年3月20日　第1刷発行

訳　者　安田徳一
発行者　野間佐和子
発行所　株式会社 講談社
〒112-8001　東京都文京区音羽2-12-21
販売部　(03) 5395-3624
業務部　(03) 5395-3615
編　集　株式会社 講談社サイエンティフィク
代表 鈴木俊男
〒162-0814 東京都新宿区新小川町9-25　日商ビル
編集部　(03) 3235-3701
印刷所　株式会社双文社印刷所・半七写真印刷工業株式会社
製本所　島田製本株式会社

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Printed in Japan

ISBN 4-06-153670-2　(KS)